

4718. (F. D. C. No. 35830. S. No. 70-880 L.)

INFORMATION FILED: 5-25-54, S. Dist. Ind., against Cassius L. Schafer (a pharmacist for Joseph F. Schafer Drug Store), Poseyville, Ind.

CHARGE: On 12-9-53, a quantity of *chloral hydrate compound* was dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 6-25-54. \$300 fine, plus costs.

4719. (F. D. C. No. 37205. S. Nos. 63-662/4 L, 63-685/6 L.)

INFORMATION FILED: 1-10-55, S. Dist. Ill., against Dale H. Bricker, t/a Border's Drug Store, Peoria, Ill.

CHARGE: Between 5-18-54 and 6-2-54, *thyroid tablets, capsules containing a mixture of secobarbital sodium and amobarbital sodium, and tablets containing a mixture of sulfadiazine, sulfathiazole, and sulfamerazine* were each dispensed once without a prescription, and *sulfisoxazole tablets and capsules containing a mixture of secobarbital sodium and amobarbital sodium* were each dispensed once upon requests for prescription refills without authorization by the prescribers.

PLEA: Guilty.

DISPOSITION: 1-12-55. \$500 fine, plus costs.

4720. (F. D. C. No. 36669. S. No. 64-281 L.)

INFORMATION FILED: 2-3-55, Dist. Alaska, against Billy C. Nelson (a pharmacist for Vista Pharmacy), Spenard, Alaska.

CHARGE: On 8-28-53, *penicillin G potassium tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 6-24-55. \$50 fine.

INDEX TO NOTICES OF JUDGMENT D. D. N. J. NOS. 4681 TO 4720

PRODUCTS

	N. J. No.		N. J. No.
Amphetamine sulfate tablets-----	4686,	Apiol, oil tansy, powdered extract	
	4688, 4690, 4693	ergot, and aloin, capsules	
dextro-, sulfate tablets-----	4681,	containing a mixture of---	4708
	4683, 4694, 4697-4699, 4701, 4703,	Benzedrine Sulfate tablets-----	4684,
	4706, 4713, 4715, 4716		4685, 4687, 4689, 4691, 4700, 4709
Amphetamine sulfate, thyroid,		Chloral hydrate compound-----	4718
atropine sulfate, aloin, and		Chloromycetin capsules-----	4709
phenobarbital; white, gray,		Dexedrine Sulfate capsules-----	4702
and pink tablets containing,		tablets-----	4685, 4691, 4692, 4705
among other ingredients-----	4695	Dextro-amphetamine sulfate tab-	
Androgenic substances-----	4702,	lets-----	4681,
	4707, 4708, 4711-4717		4683, 4694, 4697-4699, 4701, 4703,
Antrenyl Bromide tablets-----	4713		4706, 4713, 4715, 4716
Apiol, ergot, aloin, and oil penny-		Duozone tablets-----	4707
royal, capsules containing a		Emmenagogues-----	4686, 4708
mixture of-----	4686	Ergotrate Maleate tablets-----	4689

U. S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

4721-4740

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involve drugs and devices which were adulterated or misbranded within the meaning of the Act when introduced or delivered for introduction into, or while in, interstate commerce, or while held for sale after shipment in interstate commerce. These cases involve (1) seizure proceedings in which default or consent decrees of condemnation were entered and (2) criminal proceedings which were terminated upon pleas of *nolo contendere* or guilty. The seizure proceedings are civil actions taken against the *goods* alleged to be in violation, and the criminal proceedings are against the *firms or individuals* charged to be responsible for violations.

Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs.*

WASHINGTON, D. C., July 18, 1956.

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*For omission of, or unsatisfactory, ingredients statements, see No. 4727; failure to bear a label containing an accurate statement of the quantity of the contents, No. 4727; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, No. 4727; labeling information not likely to be read and understood by the ordinary individual under customary conditions of purchase and use, No. 4725.

**SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN
VIOLATIONS REPORTED IN D. D. N. J. NOS. 4721-4740**

Adulteration, Section 501 (a) (1), the article consisted in part of a filthy substance; Section 501 (a) (2), the article had been held under insanitary conditions; Section 501 (b), the article purported to be and was represented as a drug, the name of which is recognized in an official compendium (United States Pharmacopeia), and its quality and purity fell below the standard set forth in such compendium; and, Section 501 (c), the article was not subject to the provisions of Section 501 (b), and its strength differed from, and its quality fell below, that which it purported or was represented to possess.

Misbranding, Section 502 (a), the labeling of the article was false and misleading; Section 502 (b), the article was in package form, and it failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of contents; Section 502 (c), certain information required by the Act to appear on the label of the article was not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use; Section 502 (e) (2), the article was not designated solely by a name recognized in an official compendium and was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient; Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use; Section 502 (g), the article purported to be a drug the name of which is recognized in an official compendium (United States Pharmacopeia), and it was not packaged as prescribed therein; Section 502 (j), the article was dangerous to health when used in the dosage, and with the frequency and duration prescribed, recommended, or suggested in its labeling; and, Section 503 (b) (4), the article in one case was subject to Section 503 (b) (1) and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription," and in another case the label of the article bore the caution statement as quoted above, but the article was not one to which Section 503 (b) (1) applies.

**DRUGS ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED
ACCORDING TO DIRECTIONS**

4721. Vaginal suppositories (3 seizure actions). (F. D. C. Nos. 37610, 37617, 37675. S. Nos. 1-234/5 M, 6-931 M, 14-246 M.)

QUANTITY: 187 boxes at Denver, Colo., St. Louis, Mo., and Miami, Fla.

SHIPPED: Between 8-3-54 and 11-26-54, from Cleveland, Ohio, by Williams Mfg. Co.

LABEL IN PART: (Box) "Contents 6 Suppositories * * * Orange Blossom Suppositories * * * Alum-Borax-Petrolatum Prepared by Dr. J. A. McGill Co., Not Inc. 2001-3 Indiana Ave., Chicago 16, Ill."

ACCOMPANYING LABELING: Leaflet entitled "Dr. J. A. McGill Co.'s Suppositories."

RESULTS OF INVESTIGATION: Examination showed that the article contained between 44 percent and 50 percent ammonium alum.

LIBELED: Between 1-21-55 and 2-21-55, Dist. Colo., E. Dist. Mo., and S. Dist. Fla.

CHARGE: 502 (a)—the labeling of the article when shipped contained false and misleading representations that the article was an adequate and effective